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(54) Title: AUTOMATIC INJECTOR WITH ANTI-CORING NEEDLE

(57) Abstract: In one embodiment, an automatic injector comprises a cartridge adapted to contain a charge of medicament, a seal structure disposed toward a forward end of the cartridge, a plunger normally disposed in a generally rearward end of the cartridge and movable through the cartridge toward a generally forward end thereof in response to an actuating procedure. The movable plunger rearwardly confines the medicament within the cartridge. A needle normally disposed in communication with the medicament container provides a passage in which the medicament is released into an individual's flesh in response to an actuating procedure projecting the needle into the flesh of the individual. The cartridge having an increased friction region so as to slow the motion of the plunger when the forward end of the needle travels through the seal in order to eliminate coring.

AUTOMATIC INJECTOR WITH ANTI-CORING NEEDLE

CROSS REFERENCE TO RELATED APPLICATIONS

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This application claims priority from U.S. Patent Application Serial No. 09/985466, filed November 2, 2001, the disclosure of which are incorporated herein in their entirety by reference.

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BACKGROUND

1. Field of Invention

15 [0001] The present invention relates to automatic injectors, and more particularly, to automatic injectors that reduce the likelihood of coring a sealing member.

2. Discussion of Related Art

20 [0002] Automatic injectors are well known. Basically an automatic injector is a device for enabling an individual to self-administer, or administer to another, a dosage of a liquid medicament. An advantage of automatic injectors is that they contain a measured dosage of a liquid medicament in a sealed sterile condition capable of storage in such condition for an extensive period of non-use, during which period immediate injection of the stored
25 dosage may be accomplished at any time under severe emergency conditions. Another advantage of automatic injectors is the administration of the self-contained dosage of liquid medicament is accomplished without the necessity of the user initially seeing the hypodermic needle through which the liquid medicament is injected or of manually penetrating such visible needle into the
30 user's or another person's tissue.

[0003] As stated above, automatic injectors are particularly suited for use under emergency conditions. For example many tens of millions of such automatic injectors have been manufactured and sold containing nerve gas
5 antidotes for use under emergency chemical warfare conditions. Typical units which have been utilized for this purpose are disclosed in U.S. Pat. Nos 2,832,339, 3,882,863, and 4,031,893. In addition units of this type have been manufactured and used in administering anti-arrhythmic medicaments under emergency conditions relating to heart attack medical situations. The use of an
10 auto injector has also been proposed to provide other medicaments useful in treating heart attack symptoms such as clot selective thrombolytic agents (for example, tPA) and related medicaments. See for example, U.S. Pat Nos 4,689,042, 4,755,169, and 4,795, 433. In addition, automatic injectors have been widely marketed containing a dosage of epinephrine as an antidote for
15 counteracting severe allergic reactions, as for example, to bee stings, and the like.

[0004] In all of these instances, the auto-injector is specifically structured so that in its normal operation the needle extends into the tissue of
20 the individual and a specified amount of liquid medicament stored in a cartridge within the injector is injected into the tissue of the individual.

[0005] The hypodermic needle of an autoinjector has a forward end adapted to penetrate the clothing and flesh of an individual and a rearward end
25 adapted to communicate with a liquid medicament source so that the medicament is permitted to flow from the source, through the central longitudinal bore or lumen in the needle, and into the flesh of the individual. In some embodiments, the needle is contained inside the cartridge containing the liquid medicament. For example one application exists in the field of
30 automatic injection devices, wherein the liquid medicament is sealed within a

tubular container or cartridge, generally made of glass, plastic or metal, having a rubber seal closing off at the forward end and a rubber plunger at the rearward end. For example see U.S. Pat. No. 5,354,286. During an injection operation, a stressed spring assembly is released moving a push rod against the
5 plunger. The plunger pushes against the hub-end of the needle causing the needle to puncture the forward end seal of the cartridge and penetrates into the flesh of an individual. The liquid medicament is pushed at the same time through the needle, thus releasing the medicament into the individual's flesh.

10 [0006] In another type of automatic injector, the needle is connected to the forward end of the cartridge. See U.S. Pat No. 5,102,393. During an injection operation, the needle is forced through a resilient seal at the forward end of the outer housing or through an elongated rubber sheath surrounding the needle. In either case the needle is kept sterile by a seal disposed toward a
15 forward end of the housing while the injector is stored. After the needle punctures the seal or sheath, it then is forced into the flesh of the individual.

[0007] An issue that must be dealt with in each of the mentioned arrangements is that the forward end of the needle must perforate a rubber or
20 other type of seal, and it is possible for the forward end of the needle to core out or dislodge a small particle of material from the seal and potentially block the needle orifice/lumen or be forced into the individual's flesh.

25 SUMMARY OF INVENTION

[0008] To overcome these problems and others, it is proposed to provide an automatic injector in which the amount of coring by the needle is substantially reduced or eliminated.

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[0009] Therefore, in one embodiment of the present invention is to provide an automatic injector that comprises: a housing; a seal structure disposed toward a forward end of the housing; a cartridge contained within the housing; a charge of medicament contained in the cartridge; a plunger
5 normally disposed in a generally rearward end of the cartridge and movable through the cartridge toward a generally forward end thereof in response to an actuating procedure. The movable plunger rearwardly confines said medicament within said cartridge. A needle is normally disposed within the housing, the needle being projectable from a forward end of said housing
10 through said seal structure. The needle is communicable with the medicament so that movement of the plunger through the cartridge forces the medicament through the needle and into the flesh of an individual, in response to the predetermined actuating procedure. A releasable energy source is releasable in response to the predetermined actuating procedure to project the needle
15 from the forward end of the housing and slidingly drive the plunger through the cartridge in sealed relation to expel the medicament through the needle and into the flesh of an individual. The cartridge has an increased friction region so as to slow the motion of the plunger as the forward end of the needle travels through the seal.

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[0010] In another embodiment, the needle carries a damping structure for reducing the rate of acceleration of the needle by the resistance created when said damping structure moves within said medicament.

25 [0011] In addition, the present invention is directed to several automatic injection devices comprising novel needle structures that reduce coring of an elastic, plastic or rubber based structure at the forward end of the injector.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] These and other objects and advantages of the invention will become more apparent and more readily appreciated from the following
5 detailed description of the presently preferred exemplary embodiments of the invention, taken in conjunction with the accompanying drawings, of which:

[0013] Figure 1 is a longitudinal sectional view of an automatic injector according to an embodiment of the present invention;

10 [0014] Figure 2 is a longitudinal sectional view of a cartridge showing the friction region according to an embodiment of the present invention;

[0015] Figure 3 is a longitudinal sectional view of the cartridge showing the friction region according to an alternative embodiment of the present invention;

15 [0016] Figure 4 is a graph showing the force versus distance of travel of plunger in a configuration without an increased friction region, as will be described hereinafter;

[0017] Figure 5 is a graph showing the force versus distance of travel of plunger in a configuration when using embodiment illustrated in Figure 3;

20 [0018] Figure 6 is a graph showing the force versus distance of travel of plunger in a configuration when using embodiment illustrated in Figure 2;

[0019] Figure 7 is a graph showing the percentage of coring versus the inside diameter measured at an increased friction region, as will be described hereinafter;

25 [0020] Figure 8 is a graph showing the core length versus the inside diameter measured at an increased friction region, as will be described hereinafter;

[0021] Figure 9 is an enlarged view of a straight tip showing the point and the heel of the needle.

[0022] Figure 10 is a longitudinal sectional view of the hypodermic needle as installed in a cartridge according to another embodiment of the present invention; the hypodermic needle is shown having a curved tip;

[0023] Figure 11A is an enlargement of the tip of the needle according to embodiment illustrated in Figure 10 having curved "C" tip;

[0024] Figure 11B is an enlargement frontal view of the pointed tip of the needle;

[0025] Figure 12 is a longitudinal expanded sectional view of the forward end of the needle showing the interaction of the seal material with a curved tip needle having a regular/thinner wall thickness;

[0026] Figure 13 is a longitudinal expanded sectional view of the forward end of the needle show the interaction of the seal material with a needle having a heavy/thicker wall thickness;

[0027] Figure 14 is a longitudinal expanded sectional view of the forward end of the needle showing the curvature tolerance limits;

[0028] Figure 15 is a longitudinal expanded sectional view of the forward end of the needle showing the front-ground geometry;

[0029] Figure 16 is a sectional transversal view of the forward end of the needle showing the front-ground geometry;

[0030] Figure 17 is a longitudinal expanded sectional view of the forward end of the needle showing the back-ground geometry;

[0031] Figure 18 is a sectional transversal view of the forward end of the needle showing the back-ground geometry;

[0032] Figure 19 shows the consecutive transversal sectional views of the forward end of the needle illustrating the back-ground geometry;

[0033] Figure 20 shows consecutive transversal sectional views of the forward end of the needle illustrating the front-ground geometry;

[0034] Figure 21 is a longitudinal view of the forward end of the needle according to an alternative embodiment of the present invention where Parylene coating is applied to the needle;

[0035] Figure 22 is a longitudinal expanded view of the heel of needle according to embodiment illustrated in Figure 21. The heel is shown uniformly coated with a conformal coating;

5 [0036] Figure 23 is a graph showing the percentage of coring and the coring mean length versus the coating thickness as applied in embodiment illustrated in Figure 22; and

[0037] Figure 24 is a longitudinal sectional view of an automatic injector according to another embodiment of the present invention.

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DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

[0038] In the following description, for purposes of explanation and not limitation, specific details are set forth such as particular shapes and materials, mechanical components, techniques, etc. in order to facilitate a thorough understanding of the present invention. However, the invention may be practiced in other embodiments that depart from these specific details. The terms “damping structure”, “friction area”, “speed bump” and “narrowed diameter portion” are used interchangeably in this description to illustrate a feature that is used as a way to reduce the rate of acceleration thus decrease the speed at which the hypodermic needle punctures or pierces the forward seal in comparison with prior art auto-injectors. Also, for the purpose of this disclosure, the portions of the injector on the right side of Figure 1 (on the needle extension end) will be considered the front end, while the left side or activation end will be considered the rear end.

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[0039] Referring, more particularly, to the drawings in detail, there is shown in Figure 1 an automatic injector 100. The automatic injector 100 includes a tubular housing 102, a medicament cartridge assembly 104, within the forward end portion of the housing assembly 102, and a releasable energy

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source 106 which is releasable in response to a predetermined actuating procedure as will be described in detail in the following paragraphs. While the releasable energy source can be any type of assembly which effectuates an injection operation, such as a compressed gas assembly as disclosed in U.S. Patent No. 4,518,384, it is preferred that the releasable energy source be a stressed spring assembly, as generally indicated at 106. The stressed spring assembly is disposed within the rearward end portion of the housing assembly 102 in operative relation with the medicament cartridge assembly 104. A releasable end safety cap 108 positioned at the rear of the housing assembly 102 is in operative relation with the stressed spring assembly 106.

[0040] The housing assembly 102, medicament cartridge assembly 104, and stress spring assembly 106 are generally constructed in accordance with the teaching of U.S. Pat. No. 2,832,339, hereby incorporated by reference. As shown in Figure 1, the housing assembly 102 includes a cylindrical outer housing member 110 having a centrally apertured cylindrical rear wall portion 112 of reduced diameter on which the safety end cap 108 is mounted. The housing assembly 102 also includes an inner cylindrical housing member 114 within the housing member 110 within which is mounted the medicament cartridge assembly 104 and the stressed spring assembly 106. The forward portion of the inner housing member 114 is formed with a counterbore for receiving therein a cylindrical dosage container or cartridge 116 of the medicament cartridge assembly 104. The cartridge of the present invention is preferably made of metallic materials such as, but not limited to, stainless steel and aluminum. Other materials, such as plastic materials (eg., polypropylene) or glass are also within the scope of the present invention.

[0041] The forward end of the container or cartridge 116 is closed by a stopper or seal 118, preferably, of suitable rubber or compliant plastic material. The cartridge assembly 104 is retained in closing relation with the

forward end of the inner housing member 114 by a housing end cap member 120 of molded plastic material. The cap 120 is preferably retained on the inner housing member 114 by inter-engagement of a pair of ridges 122 formed on the exterior periphery of the tubular member 114 with an annular groove 124
5 formed on the interior periphery of the cap member 120. The rearward end of the cartridge 116 is closed by a rubber or plastic plunger 126 which is slidably, sealingly engaged with the inner surface of cartridge 116 so as to enclose within the cartridge a dosage 128 of a liquid medicament.

10 [0042] A hypodermic needle 130 is disposed within the cartridge 116. It thus can be appreciated that the cartridge assembly 104 includes cartridge 116, seal 118, needle 130 and disc 132. As can be discerned from FIG. 1, needle 130 is normally stored in contact with the medicament 128. However, in the broadest aspects of the present invention, it can be appreciated that
15 needle 130 can be disposed in a separate chamber (either evacuated or filled with a preferably inert gas) forwardly of the medicament 128 (for example, see our U.S. Pat. No. 5,085,642 and 5,102,393), so long as the needle is somehow communicable with the medicament in a manner which permits the medicament to travel through the needle and into the flesh of an individual.
20 The needle can also be disposed in contact with one of two medicaments, which are normally stored separately within the injector and then either mixed within the injector prior to an injection (e.g. see U.S. Pat. No. 5,041,088) or injected separately one after the other (see U.S. Pat. No. 5,092,843). The hypodermic needle 130 is preferably made from stainless steel.

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 [0043] In the present embodiment, the needle 130 has its pointed end disposed within a recess formed in the seal 118. A disc 132 of plastic is disposed within the forward end of the cartridge 116 in surrounding, securing and guiding relation with the hypodermic needle 130 and in abutting
30 engagement with the seal 118. The disc 132 serves to releasably hold the

needle in its storage position to provide peripheral centering therefore during the dosage injecting stroke of the plunger 126. The rearward end of the hypodermic needle 130 is enlarged for engagement by the plunger and has a slot 134 formed in its side wall adjacent the enlarged end for communicating the dosage 128 with the hollow interior of the hypodermic needle 130 when the plunger 126 is in engagement therewith. The inner housing member 114 is mounted within the outer housing member 110 for limited reciprocating movement as determined by a pair of ridges 136 formed on the exterior periphery of the tubular inner housing member 114 at a position spaced rearwardly from the pair of ridges 122. The pair of ridges 136 is adapted to engage with an elongated annular groove 138 formed on the interior periphery of the outer housing member 110.

[0044] The stressed spring assembly 106 includes a normally compressed but releasable coil spring 142 and an elongated collet member 140. The collet member is disposed within the rearward portion of the housing member 114 and has its forward end disposed adjacent to the plunger 126. The forward end of the collet member 140 has a flange 141 configured to engage the forward end of the stressed coil spring 142, which surrounds the central portion of the elongated collet member 140. The collet 140 has its rearward end engaged with a locking ring 152 sitting on an annular end flange 144 formed integrally on the rearward end of the inner housing member 114.

[0045] The rearward end of the elongated collet member 140 are split to provide a plurality (e.g., four) flexible spring fingers 146, the rearward extremities of which are formed with rearwardly and outwardly facing cam releasing surfaces 148. Extending inwardly from the rearward end of each cam surface 148 is locking shoulder 150 adapted to engage a locking ring 152 seated on the rear surface of flange 144. The forward portion of the apertured cylindrical wall portion 112 is formed with a complementary cam surface 154,

which is disposed in engagement with the cam surfaces 148 so as to effect a laterally inward movement of the spring fingers 146 toward one another to disengage locking shoulders 150 from locking ring 152 in response to a relative forward actuating movement of the outer housing member 110 with
5 respect to the inner housing member 114. This inward action of the spring fingers 146 is permitted only after the safety cap 108 is removed, as will be described.

[0046] The operation of the injector will now be described. In the first
10 step of operation, releasable end cap 108 is removed from the injector 100. This removal is accomplished simply by gripping the exterior periphery of the end cap 108 and moving it rearwardly while gripping and holding the outer housing member 110. The cap member 108 carries with it a safety pin portion 160. With the safety pin portion 160 removed from its safety position, which
15 normally prevents the laterally inward movement of the spring fingers 146, the user can now complete the operation by moving the forward cap member 120 into contact with the tissue of a person to be injected. By applying a continued forward force on the exterior periphery of the outer housing member 110, cam surfaces 154 thereof are moved forwardly. This forward movement in
20 cooperation with the cam surfaces 148 on the spring fingers 146 causes the locking surfaces 150 of the latter to move inwardly off of the locking ring 152, thus releasing the stressed spring 142. The spring 142 acts through the collet member 140 to move the same forwardly which has the effect of moving the plunger 126 with it. As the plunger moves forwardly, it carries with it the
25 needle 130. The pointed forward end of the needle pierces through the seal 118 and into the tissue of the patient. At the same time, the dosage 128 of liquid medicament within the cartridge 116 is caused to move inwardly into the slot 134 of the needle and outwardly of the pointed forward end thereof as the same moves into the tissue of the user.

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[0047] Referring more particularly to Figure 2A, describing in more detail the cartridge assembly 104. The hypodermic needle 202 comprises an elongated tube, generally cylindrical terminated at the rearward end by hub 206. The forward end of the needle has a pointed shape 208, shown in more detail in enlarged Figure 2B. The needle 202 is maintained along a longitudinal axis X with holder 210. Needle 202 is shown housed inside cartridge 212, containing a liquid medicament. However as stated previously needle 202 need not be inside cartridge 212 but can be arranged to be outside the medicament cartridge. The forward end of cartridge 212 is terminated by seal 214 to keep the liquid medicament from leaking, shown in more detail on Figure 2B. The pointed end 208 of needle 202 is oriented toward seal 214. Therefore, initially the needle 202 is disposed between plunger 204 and seal 214. The plunger is shown in this figure as a one piece material, however it is understood that the plunger can be made of a plurality of pieces with various ductile constants such as a harder piece and a softer piece of rubber.

[0048] Seal 214 is made of a flexible material, such as but not limited to, rubber. It is known that polymers behave in a ductile manner when strained at low speed and behave in a brittle manner when strained at high speed.

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[0049] In order to substantially reduce or eliminate coring, the needle 202 is arranged to penetrate in a "gentle" manner into the rubber seal 214 by reducing the thrust of the needle. Cartridge 104 has a friction region 215 for slowing the motion of plunger 204 thus reducing the rate of acceleration of needle 202 when perforating seal 214. The acceleration rate is reduced so that the speed of the needle is less than 680 inches/s when the needle pierces the seal. The reduction in acceleration rate is intended specifically to reduce the speed to a level at which coring will not occur. Preferably, the speed at which the seal is pierced is also greater than 150 inches/s so that the injection operation is not delayed more than what is desirable. The friction region in

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this embodiment is a narrowed diameter portion or localized narrowed diameter portion 222 in the wall 224 of cartridge 212. The narrowed diameter portion 222 also referred to as speed bump is arranged between seal 214 and plunger 204. The narrowed diameter portion 222 is arranged and configured to
5 reduce acceleration of plunger 204, thus reducing the speed at which the needle 202 would otherwise travel when the needle tip 208 travels through seal 214. The narrowed diameter portion 222 is created on the wall of the cartridge 212 with a pressure forming method, for example with a clamshell die. The die or a rolling process can be used to imprint a selected shape to the
10 stainless wall of cartridge 212. For example cylindrical rounded narrowed diameter portion around the cylindrical wall of the cartridge can be imprinted.

[0050] The localized narrowed diameter portion 222 in the wall 224 of cartridge 212 acts as a “speed bump” by slowing down the motion of plunger
15 204. Indeed, the narrowed diameter portion 222 increases the normal force between the plunger periphery and the wall 224 of cartridge 212, thus creating a frictional force counter to the plunger’s movement. The narrowed diameter portion 222 increases the diametrical interference thereby increasing the friction and retarding plunger 204 movement. This slowed movement causes
20 the needle 202 to strain the seal 214 in a more ductile mode, thus leading to a substantial reduction in coring.

[0051] The speed bump is arranged to be only effective along a partial length of the cartridge 212. This allows the plunger to receive the full spring
25 force at the beginning of operation helping to overcome static friction between the plunger 204 and the cartridge 212. The speed bump then takes effect immediately prior to the front end of the needle contacts the seal 214. After the needle tip 208 completes its penetration of the seal 214, the speed bump disengages making the full spring force available to ensure completeness of
30 the injection process.

[0052] The plunger 204 meets increased resistance when the plunger 204 reaches the narrowed diameter portion 222. Plunger 204 has a plurality of ribs 230 as shown in Figure 2C. Each time a rib 230 of the plunger 204
5 encounters an edge of narrowed diameter portion 222 the friction force is increased thus leading to a net decrease in injection acceleration rate.

[0053] In another embodiment, illustrated in Figure 3A, the friction region 300 comprises a corrugated configuration comprising a plurality of
10 projections 302, shown enlarged in Figure 3B, in order to multiply the interference with the plunger 304.

[0054] It is to be understood however, that friction region 300 can be any structure of the cartridge that slows plunger 304. While in the
15 embodiments shown it is the wall of the cartridge itself that performs this function, it should be appreciated that the cartridge may employ a separate structure inserted therein. The plunger 304 meets increased resistance when the plunger's leading rib crosses the friction region leading edge. The rippled shape of friction region 300 illustrated in Figure 3 exchanges some of the
20 aforementioned diameter decrease in the previous embodiment in exchange for a multitude of leading edges.

[0055] To demonstrate the effectiveness of the present invention in substantially reducing formation of cores, a series of tests are implemented
25 and data is acquired.

[0056] Figure 4 shows the force-distance data profile of a standard cartridge-plunger. The curve 400 exhibits a high static friction spike 402 followed by a constant kinetic friction stage 404. Numerous tests are run to
30 collect statistical data. The mean kinetic friction from the statistical data is

determined to be 0.54 lb. The nearly vertical spike 406 at the terminus represents bottoming of the plunger against the seal.

[0057] Figure 5 shows the force-distance data profile of a cartridge having corrugated portion and a plunger, as illustrated in Figure 3. The portion of travel in which the ripples are in effect is clearly visible on curve 500. The "spikiness" of data at the friction phase 502 is caused by the individual matings and separations of the individual ripples with plunger ribs. Similarly statistical data is acquired to allow calculation of the mean kinetic friction during the speed bump phase. The mean kinetic friction is determined to be 1.47 lb. The mean kinetic friction of the post speed bump phase, shown on Figure 5 as phase 504, is 0.52 lb.

[0058] Figure 6 shows the force-distance data profile 600 of a smooth speed bump and a plunger having three ribs, as illustrated in Figure 2. The three large consecutive spikes 602 are caused by the three ribs of the plunger entering the speed bump. The smaller spikes 604 occur as the plunger's ribs exit the speed bump. Similarly statistical data is acquired to allow calculation of the mean kinetic friction during the speed bump phase. The mean kinetic friction during the speed bump phase is determined to be 1.71 lb. The mean kinetic friction of the post-speed bump phase, shown on figure 6 as phase 606, is similar to the data described previously.

[0059] Data is also acquired to demonstrate that the introduction of the speed bump reduces coring. Figure 7 shows the coring frequency versus the inside diameter of the cartridge at the speed bump. The highest point on the curve corresponds to the inside diameter 0.298" of the cartridge without a speed bump. At this size (without a speed bump) approximately 70% of units tested produced cores. The lowest point on the curve corresponds to the

smooth (without ridges) speed bump in its intended diameter of 0.278".

Statistical data showed a population of less than 1% revealed coring.

5 **[0060]** In the case of a cartridge with a speed bump, a softer spring for pushing the plunger, may be used if desired to allow a smoother transition from the diameter of cartridge without the bump to the diameter of the cartridge at the bump.

10 **[0061]** In addition to coring frequency, the diameter of the particles generated by coring are also measured and reported in Figure 8. As seen in Figure 8, the dimension of the core (particle) decreases when the inside diameter of the cartridge at the speed bump decreases. Therefore, the speed bump has also an advantage in decreasing the size of the coring particles.

15 **[0062]** These tests are carried out for a straight tip needle such as shown in Figure 9 (which is a simplified view of the needle of Figure 3A). Needle tip 900 has generally a point 902 and a heel 904. As can be seen in the following embodiments the needle tip can have a curved shape instead of a straight shape as in Figure-9.

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[0063] Figure 10 shows a longitudinal sectional view of the automatic injector with hypodermic needle according to another embodiment of the present invention. The hypodermic needle 1000 is shown having a curved tip 1002. As mentioned previously, and now illustrated in Figure 11A, the curved leading edge 1002 of needle 1000 having a C-tip configuration pushes the material of the seal 1004 far enough away from the heel 1100 to prevent intimate contact. The curved arrow 1102 indicates the direction of flow of seal material relative to the movement of the needle 1000. The arrow indicates in particular that the seal material flows around the curved tip 1002.

25 In other words, the curved tip 1002 acts as a shield for the orifice or lumen

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1104 of needle 1000, by blocking the seal material 1004 from penetrating through the orifice 1104. The extent to which the needle tip is curved over the orifice influences seal coring frequency.

5 **[0064]** Figure 11B shows an enlargement frontal view of the pointed tip 1110 of the needle. The curved forward tip 1114 is shown completely shielding lumen 1112 thus protecting lumen 1112 of being in direct contact with the seal material as previously discussed. In other words, the bent tip 1114 shields the entire cross-section of the longitudinal passage in the needle.

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[0065] Figure 12 shows the interaction of seal material 1200 with needle 1202 having a regular wall thickness, preferably between 0.0055 inch and 0.0065 inch. Figure 13 show the interaction of seal material 1300 with needle 1302 having a thicker wall (heavy wall) preferably between 0.0083
15 inch and 0.0090 inch. In particular, Figure 13 illustrates that in the case of needle with heavy wall thickness 1302, the heel 1304 is further away from the seal material 1300, thus further reducing coring potential compared to needle with regular wall thickness 1202. Testing shows that in the eventuality cores are produced, cores are generally smaller when using heavy-wall needles
20 versus regular wall needles of similar geometry.

[0066] Figure 14 shows the geometry of the C-tip needle 1400 with manufacturing limits for the hard C-tip geometry. The needle comprises a hollow rigid tubing 1401 having a cylindrical wall defining a longitudinal
25 passage. The cylindrical wall includes first and second opposing wall portions. First wall portion is illustrated in this figure by longitudinal cross-section 1404 and second wall portion is illustrated in this figure by longitudinal cross-section 1406. The first wall portion 1404 has a forward tip portion 1408 terminating in a forward end tip 1410. The second wall
30 portion 1406 terminating at a position 1412 rearwardly spaced from the end tip

1408. The forward tip portion 1408 is bent at angle 1414. Angle 1414 is defined as the angle between tangent 1416 to curvature of the outer surface at the end tip 1410 and the longitudinal axis 1418 of needle 1400. In one embodiment, the forward end tip 1410 terminates in a region defined by an
5 imaginary forward extrapolation of the thickness of second wall 1406 defined by limits 1422 and 1424 which are intended to insure that the end tip 1410 is always deflected far enough to always shield the lumen or opening 1420, but not deflected so far to hinder the penetration or withdrawal of the needle (this applies equally to the embodiment of Figure 17). Other C-tip geometry is the
10 soft C-tip needle where the tip is deflected such that it is aligned with the cannula centerline or longitudinal axis 1418. The soft C-tip geometry does not reduce coring as well as the hard C-tip geometry of needle 1400 of the present invention.

15 **[0067]** The hard C-tip needle is manufactured according to the following process: Two-meter length of tubes are bundled and are cut to the cannula blank length. The ends of the tubes are de-burred and the tubes cleaned. The tubes are then automatically fed and automatically taped onto 18
20 inch grinding fixtures. The tubes on the grinding fixtures are placed on a grinding machine where a primary grind facet is applied. The tubes are then inclined and rotated to grind a second facet and inclined and rotated again to grind a third facet. The second and third facets are preferably symmetrical to one another. The cannula needle tip are rolled over to produce the curved hard
25 "C" tip. The cannula are de-burred again and an anti-coring micro-blast is applied to the heel. The micro-blast may alternately be applied before bending. The cannula are electro or chemically polished then cleaned, dried, passivated and inspected before packaging. The cannula are packaged with the points/tips oriented in the same direction and wrapped in non-shedding
30 paper to be placed in a polyethylene bag and into a foam line carton for distribution.

[0068] All hypodermic needles have primary and secondary facets.

The secondary facets are called lancets. Figure 15 shows a sectional longitudinal view of a C-tip needle 1500. Lancets 1502 are shown in relation to the primary bevel 1504. A sectional transversal cut 16 of the tip 1508 is shown in Figure 16 with a front ground where the tip 1508 is ground from the inside as shown on transversal cut 1600. Figure 17 shows a sectional longitudinal view of a C-tip needle 1700. Lancets 1702 are shown in relation to the primary bevel 1704. A sectional transversal cut 18 of the tip 1708 is shown in Figure 18 with a back ground where the tip 1708 is ground from the outside as shown on transversal cut 1800. Back-ground lancets bring advantages to a C-tip needle. An advantage is that the angled lancets may serve to further direct seal material away from the lumen. Another advantage is that the effectively narrower thus sharper leading edge may cut through clothing and skin or tissue more easily. The use of heavy-wall cannulas provides more wall thickness allowing a better optimization of the geometry of the back-ground lancets.

[0069] Figure 19 shows the consecutive transversal cross sectional views of the needle tip 1900 in a case of a Hard-C tip needle with a back ground geometry. In one embodiment, the length of the needle is 1.343", the inside diameter 1906 is between 0.0138 inch and 0.0154 inch and the outside diameter 1908 is between 0.0280 and 0.0285. The tip 1900 is shown with consecutive transversal cross sectional views AA, BB, CC, DD, EE, FF, GG, MM displayed in Figures 19A, 19B, 19C, 19D, 19E, 19F, 19G and 19M. Figure 19A shows the transversal cut AA having the shape of a disc corresponding to the tube/cylindrical form of the needle. Further along approaching the tip of the needle, Figure 19D shows the cross-section DD with the back grinds 1910 at an angle of 120° in relation to the base line 1912.

Other embodiments with a back grind with an angle of 130° are also within the scope of the present invention.

[0070] Figure 20 shows the consecutive transversal cross sectional
5 views of the needle tip 2000 in a case of a Hard-C tip needle with a front
ground geometry. In one embodiment, the length of the needle is 1.343", the
inside diameter 2002 is between 0.0155 inch and 0.0170 inch and the outside
diameter 2004 is between 0.0280 and 0.0285. The tip 2000 is shown with
consecutive transversal cross sectional views AA, BB, CC, DD, EE, FF, MM
10 displayed in Figures 20A, 20B, 20C, 20D, 20E, 20F, 20M. Figure 20A shows
the transversal cut AA having the shape of a disc corresponding to the
tube/cylindrical form of the needle, notice the cylindrical wall of the needle is
thinner than in the previous embodiment. Further along approaching the tip of
the needle, Figure 20D shows cross-section DD with the front grinds 2010 at
15 an angle of between about 25° and 35° and preferably 30° in relation to the
base line 2015.

[0071] Tests show that the hard C-tip needle configuration can
substantially eliminate coring when used in conjunction with softer springs
20 that allow the tip of the needle to "flow" more easily inside the seal material.
Combination of geometry elements for the C-tip such as back-ground
geometry and hard C-tip configuration in conjunction with the use of softer
springs, having a K spring constant between 1.5 lb/in and 6.5 lb/in, more
preferably between 3 lb/in and 5 lb/in, provides enhanced performance of the
25 needle in reducing coring.

[0072] Figure 21 shows a longitudinal sectional view of the needle tip
2100 coated with a conformal coating 2200 (shown in Figure 22). A
conformal coating is coating that conforms to the shape of the substrate while
30 allowing blunting of sharp edges. In one embodiment, conformal coating

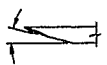
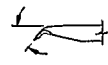
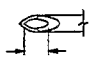

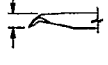
2200 consists of a Parylene coating (shown in Figure 22). Parylene is a registered trademark of polyparaxylylene coating, manufactured by Specialty Coating Systems, Inc. of Indianapolis, Indiana. The application of Parylene in coating an injection device and needle is described in US Pat. 5,354,286 which is incorporated herein by reference. Figure 22 shows a close up view of needle heel 2102. Membrane coring occurs when the needle heel 2102 cuts the outer surface of the seal. A rounded, or blunted, edge on the heel alleviates coring. Standard needles receive an abrasive blast during manufacturing however this blast is not sufficient since standard needles still create cores. Tests show that Parylene coating 2200 conforms well to the substrate geometry, including edges, for example edge 2202, as shown in Figure 22.

[0073] Parylene coating is applied at various thicknesses ranging from 0.0001 to 0.001 inch. Data collected in the study of effect of Parylene coating thickness on coring is summarized in graph shown in Figure 23. The graph particularly shows that Parylene coating overall decreases the likelihood of coring as well as decreases the size of the core. However, as seen on the graph, increasing the coating thickness beyond around 0.0005'' does not help in decreasing coring but acts in the opposite manner by increasing coring. Indeed, the graph in Figure 23 clearly shows a curve minimum indicating that the optimum thickness of the coat accomplishing the desired results is a Parylene coating thickness around 0.0005''. In addition, tests have shown that the use of a spring having a spring constant between 1.5 lb/inch and 6.5 lb/inch in conjunction with the use of a needle coated with Parylene is particularly beneficial in reducing coring.

[0074] Figure 24 shows a longitudinal sectional view of a cartridge assembly 2400 used in an automatic injector according to another embodiment of the present invention. Automatic injector uses an alternative mechanism for

reducing the rate of acceleration of the needle thus slowing down the speed of the needle in comparison with prior art devices. The acceleration rate is reduced so that the speed of the needle is less than 680 inches/s when the needle pierces the seal. The reduction in acceleration rate is intended specifically to reduce the speed to a level at which coring will not occur. Preferably, the speed at which the seal is pierced is also greater than 150 inches/s so that the injection operation is not delayed more than what is desirable. Indeed, damping disk 2402 attached to needle 2404 is used to reduce the rate of acceleration of needle 2404 by the friction generated when disk 2402 flows inside liquid medicament 2406. In other words, the flow resistance generated by the viscosity of the fluid liquid medicament against the movement of damping disk 2402 acts to reduce the rate of acceleration of needle 2404. Therefore, similarly to the previous embodiments, the damping disk plays the role of friction for slowing the tip of the needle, hence ultimately to substantially eliminating coring.

[0075] The Table below shows examples of geometries for various embodiments of the tip of the needle. The primary angle is selected between 13 to 18 degrees. The bend angle, that is the angle between a tangent to a curvature of the outer surface of the end tip of the needle and a longitudinal axis of the needle, is selected to be between 51° and 100°, preferably between 85° and 95°, most preferably 90° (Figure 14 shows a bend angle of approximately 63° and Figure 17 shows a bend angle of approximately 90°). The tip offset in relation to the wall of the needle is between .024 and .026 inches. The opening length is selected between .033 and .055 inches. The inside diameter is selected between .011 and .016 inches. The ratio length of opening to outside diameter of passage is between 1.7 to 2.2.

	Primary Angle (deg)	Bend Angle (tangent @ tip) (deg)	Opening Length (in)	Inside Diameter (in)	Ratio, L/OD	Tip Offset (in)
						
10010 (Hard-C)	14	63, 81	.061	.016	2.2	.026
10014 (HC, Heavy Wall)	13	51, 81	.049	.015	1.7	.024
10017 (HC, HW, Back Ground)	16.5	90, 90	.063	.015	1.9	.024
10018 (HC, HW, BG, B-tip)	13	90	.053	.011	1.9	.024

[0076] While the invention has been described in connection with particular embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary it is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention as defined by the claims, which follow.

WE CLAIM:

1. An automatic injector comprising:
 - a housing having a rearward end and a forward end;
 - a seal structure disposed toward the forward end of said housing;
 - a cartridge contained within said housing;
 - a charge of medicament contained in said cartridge;
 - a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;
 - a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; and
 - a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidingly drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual, said cartridge having an increased friction region so as to slow the motion of said plunger as the forward end of the needle travels through said seal.
2. The automatic injector as claimed in claim 1,
 - wherein said seal structure seals a forward end of said cartridge.
3. The automatic injector as claimed in claim 1,
 - wherein said friction area comprises a narrowed diameter portion in a wall of said cartridge.
4. The automatic injector as claimed in claim 1,
 - wherein said friction area is a corrugated portion in a wall of said cartridge.

5. The automatic injector as claimed in claim 1,
wherein a tip of said needle is coated with polyparaxylylene.
6. The automatic injector as claimed in claim 5,
wherein said polyparaxylylene coating has a thickness between about 0.0001 to 0.001 inches.
7. The automatic injector as claimed in claim 1,
wherein said needle is normally stored within said cartridge, in contact with said medicament.
8. The automatic injector as claimed in claim 1,
wherein said needle comprising:
a hollow rigid tubing having a cylindrical wall, the cylindrical wall having an inner surface and outer surface;
a lumen opening having a front pointed portion comprising a lancet shaped tip having a facet grinding at an angle;
said tip is bent in a curve directed toward a longitudinal axis of said cylindrical wall in manner as to constitute a shield to said lumen opening.
9. The automatic injector as claimed in claim 8,
wherein said tip comprises primary and secondary facets, said secondary facets ground at an angle at the inside surface of the needle.
10. The automatic injector as claimed in claim 8,
wherein said tip comprises primary and secondary facets, said secondary facets ground at
an angle at the outside surface of the needle.

11. The automatic injector as claimed in claim 1,
wherein said plunger comprises a material selected from the group of plastics and rubbers.
12. The automatic injector as claimed in claim 3,
wherein said plunger comprises ribs arranged to reduce the rate of acceleration of said needle when in contact with said friction region.
13. The automatic injector as claimed in claim 4,
wherein said plunger comprises ribs arranged to reduce the rate of acceleration of said needle when in contact with said friction region.
14. The automatic injector as claimed in claim 11,
wherein said plunger comprises a plurality of materials having different ductilities, said materials are selected to interact differently with said friction area to reduce the rate of acceleration of said needle.
15. The automatic injector as claimed in claim 1,
wherein said releasable energy source comprises a normally compressed spring which is released in response to said predetermined actuating procedure.
16. The automatic injector as claimed in claim 15,
wherein said spring having a spring constant between 1.5 lb/in and 6.5 lb/in.
17. The automatic injector as claimed in claim 1,
wherein said seal structure comprises a material selected from the group of plastics and rubber.
18. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;

a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;

a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; wherein said needle comprises a damping structure for reducing the rate of acceleration of said needle by the viscous resistance created when said damping structure moves within said medicament; and

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

19. The automatic injector as claimed in claim 18,

wherein said damping structure comprises a damping disk attached to said needle and arranged to reduce the rate of acceleration of said needle by the flow resistance created when said disk moves through said medicament.

20. An automatic injector comprising:

- a housing having a rearward end and a forward end;
- a seal structure disposed toward the forward end of said housing;
- a cartridge contained within said housing;
- a charge of medicament contained in said cartridge;

a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;

a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said

medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip, said forward tip portion being bent in a manner to shield the entire cross-section of said longitudinal passage;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

21. The automatic injector as claimed in claim 20,
wherein said seal structure seals a forward end of said cartridge.
22. The automatic injector as claimed in claim 20,
wherein the tip of said needle is coated with polyparaxylylene.
23. The automatic injector as claimed in claim 22,
wherein said polyparaxylylene coating has a thickness between about 0.0001 to 0.001.
24. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;
a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;
a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable

with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip, said forward tip portion being bent in a manner to shield the entire cross-section of said longitudinal passage; wherein said forward tip portion is bent at an angle approximately between 51 degrees and 100 degrees; said angle being defined as the angle between a tangent to a curvature of a outer surface at said end tip and a longitudinal axis of said needle;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

25. The automatic injector as claimed in claim 24,
wherein said seal structure seals a forward end of said cartridge.
26. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;
a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;
a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said

medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip, said second wall has a thickness, and said forward end tip terminates in a region defined by an imaginary forward extrapolation of said thickness; said forward tip portion is bent at an angle approximately between 51 degrees and 100 degrees; said angle being defined as the angle between a tangent to a curvature of an outer surface at said end tip and a longitudinal axis of said needle;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

27. The automatic injector as claimed in claim 26,
wherein said seal structure seals a forward end of said cartridge.

28. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;
a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;

a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said

medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip, said forward tip portion being bent in a manner to shield the entire cross-section of said longitudinal passage; said needle comprises an enlarged rearward portion constructed and arranged for engagement with said plunger;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

29. The automatic injector as claimed in claim 28,
wherein said seal structure seals a forward end of said cartridge.

30. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;
a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;

a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip; said forward tip portion is bent at an angle approximately between 51 degrees and 100 degrees; said angle being defined as the angle between a tangent to a curvature of an outer surface at said end tip and a longitudinal axis of said needle; wherein said needle comprises an enlarged rearward portion constructed and arranged for engagement with said plunger;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidingly drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

31. The automatic injector as claimed in claim 30,
wherein said seal structure seals a forward end of said cartridge.
32. An automatic injector comprising:
 - a housing having a rearward end and a forward end;
 - a seal structure disposed toward the forward end of said housing;
 - a cartridge contained within said housing;
 - a charge of medicament contained in said cartridge;
 - a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;
 - a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; said needle comprising:

a hollow rigid tubing having a cylindrical wall defining a longitudinal passage therethrough, said cylindrical wall including opposing first and second wall portions, said first wall portion having a forward tip portion terminating in a forward end tip, said second wall portion terminating at a position rearwardly spaced from said end tip, said forward tip portion being bent in a manner to shield the entire cross-section of said longitudinal passage; said forward tip portion is bent at an angle approximately between 51 degrees and 100 degrees; said angle being defined as the angle between a tangent to a curvature of an outer surface at said end tip and a longitudinal axis of said needle; said needle comprises an enlarged rearward portion constructed and arranged for engagement with said plunger;

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidingly drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual.

33. The automatic injector as claimed in claim 32, wherein said seal structure seals a forward end of said cartridge.

34. An automatic injector comprising:
a housing having a rearward end and a forward end;
a seal structure disposed toward the forward end of said housing;
a cartridge contained within said housing;
a charge of medicament contained in said cartridge;
a plunger normally disposed in a generally rearward end of said cartridge and movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge;

a needle normally disposed within said housing, said needle being coated with polyparaxylylene, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure; and

a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidingly drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual;

wherein said releasable energy source comprises a spring having a spring constant between approximately 1.5 lb/inch and 6.5 lb/inch.

35. A method for injecting a medicament with an automatic injector, which injector comprises a housing, a seal structure disposed toward a forward end of said housing, a cartridge contained within said housing, a charge of medicament contained in said cartridge, a plunger movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge, a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure, a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidingly drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual;

said method comprising:

releasing said energy source;

accelerating said needle forwardly within said housing;

reducing the rate of acceleration of said needle prior to said needle penetrating said seal; and

expelling said medicament through said needle.

36. The method for injecting a medicament with an automatic injector as recited in claim 35,

wherein said penetrating said seal is performed at a speed between 250 inches/s and 680 inches/s.

37. The method for injecting a medicament with an automatic injector as recited in claim 35, further comprising:

speeding up said needle after said needle has fully penetrated said seal.

38. A method for injecting a medicament with an automatic injector, which injector comprises a housing, a seal structure disposed toward a forward end of said housing, a cartridge contained within said housing, a charge of medicament contained in said cartridge, a plunger movable through said cartridge toward a generally forward end thereof in response to an actuating procedure, said movable plunger rearwardly confining said medicament within said cartridge, a needle normally disposed within said housing, said needle being projectable from the forward end of said housing through said seal structure, said needle being communicable with said medicament so that movement of said plunger through said cartridge forces said medicament through said needle and into the flesh of an individual in response to said predetermined actuating procedure, a releasable energy source releasable in response to said predetermined actuating procedure to project said needle from the forward end of the housing and slidably drive said plunger through said cartridge in sealed relation to expel said medicament through said needle and into the flesh of an individual;

said method comprising:

releasing said energy source;

moving said needle forwardly within said housing at a speed of less than 680 inches/s as said needle penetrates said seal; and

expelling said medicament through said needle.

39. A method for injecting a medicament with an automatic injector as recited in claim 38,

wherein said method comprises moving said needle forwardly within said housing at a speed of more than 150 inches/s as said needle penetrates said seal.

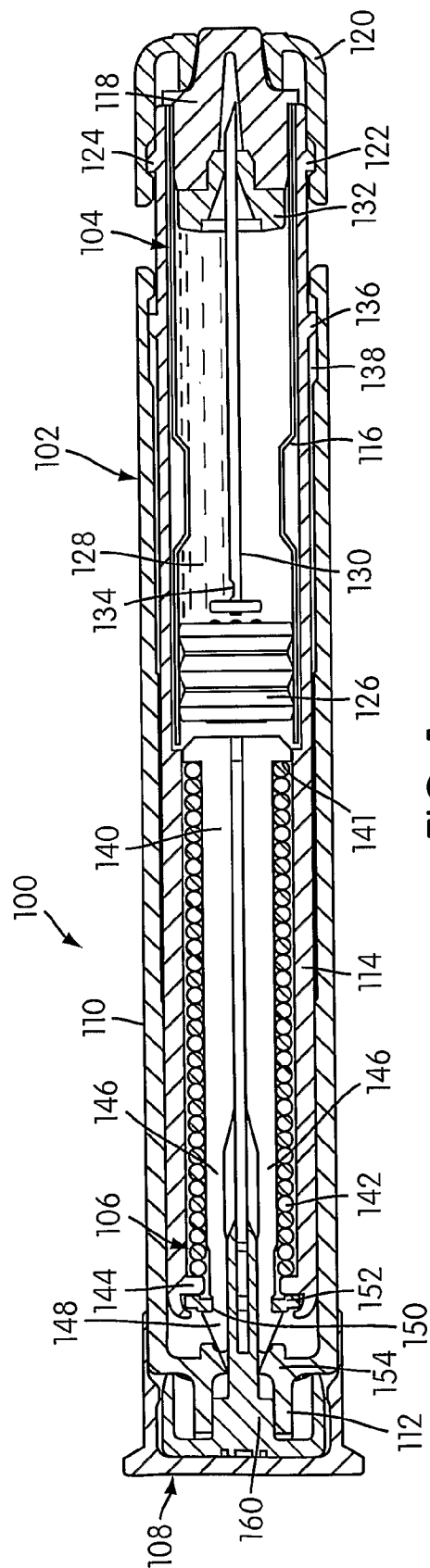
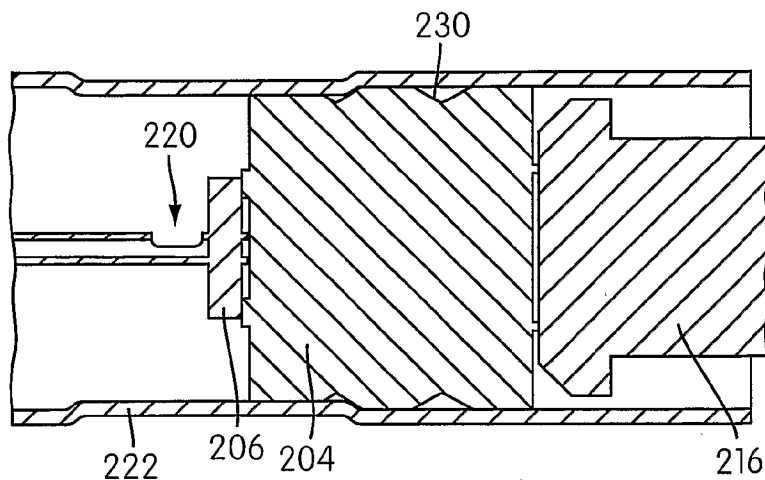
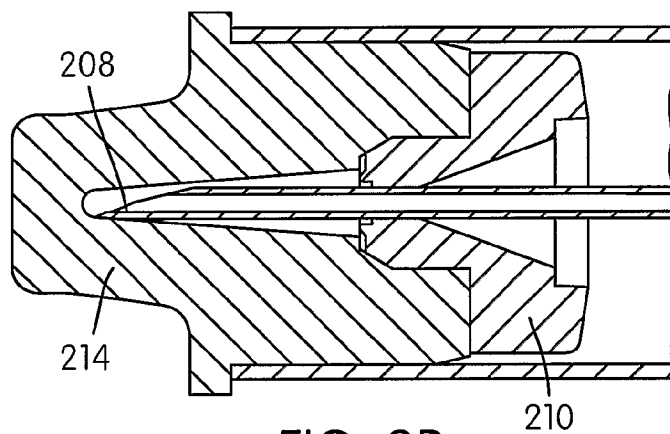
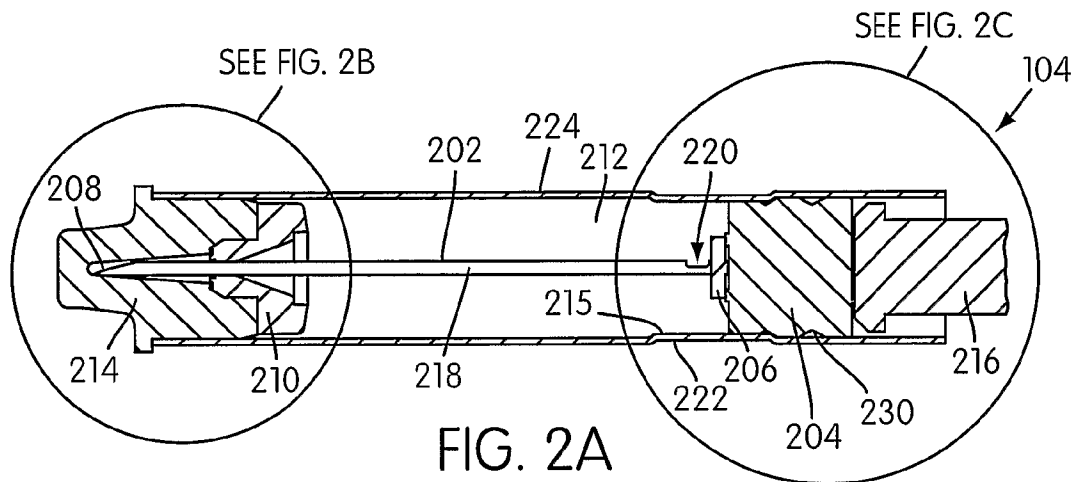
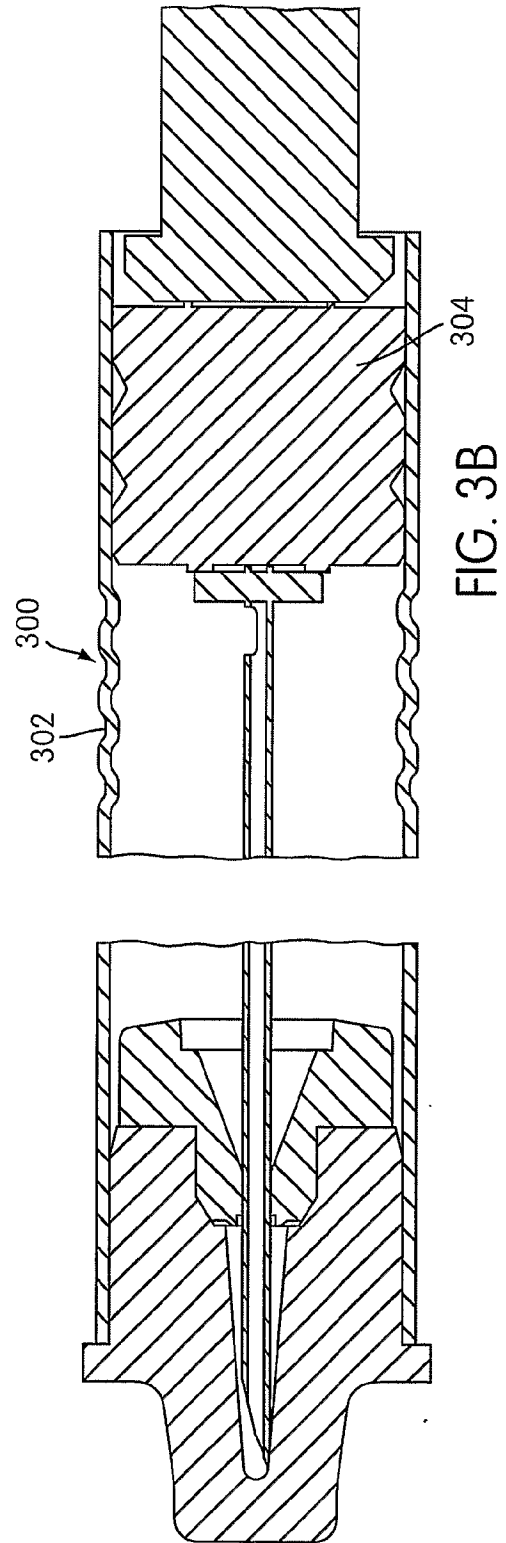
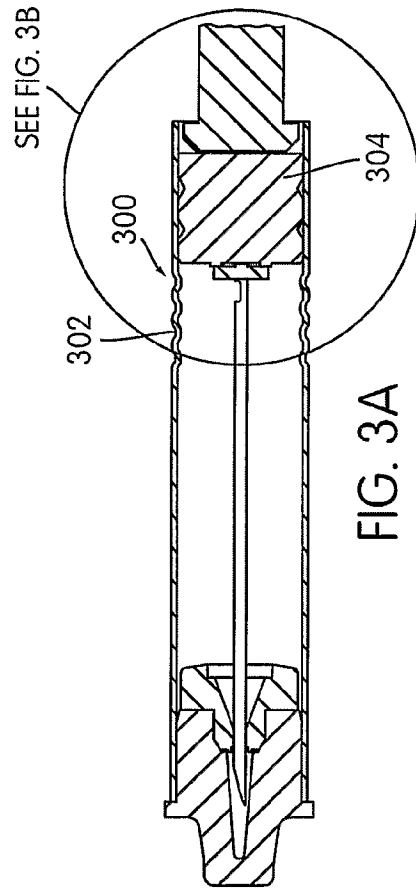


FIG. 1

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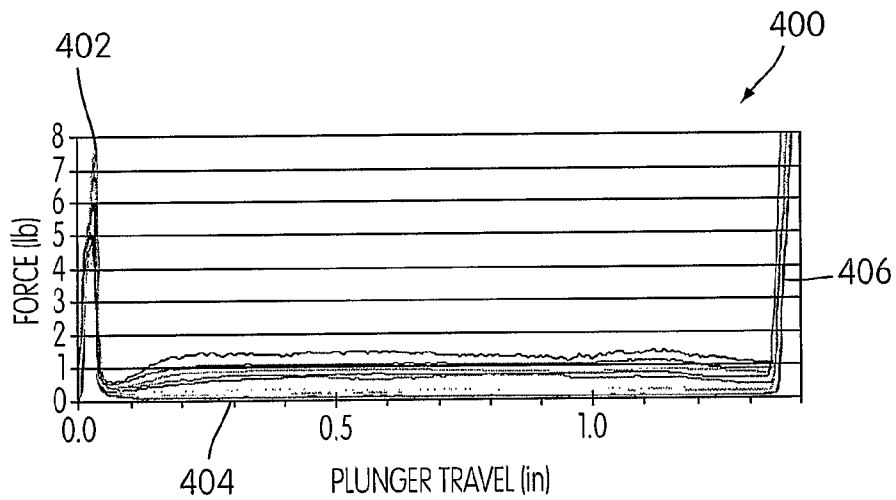


FIG. 4

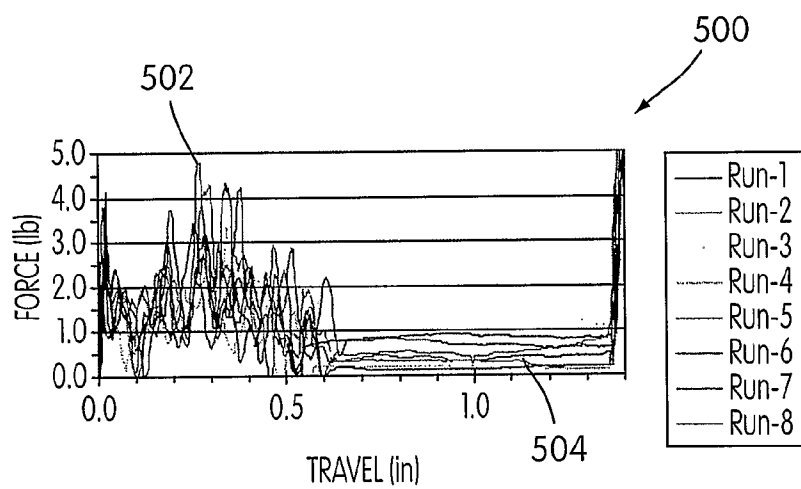


FIG. 5

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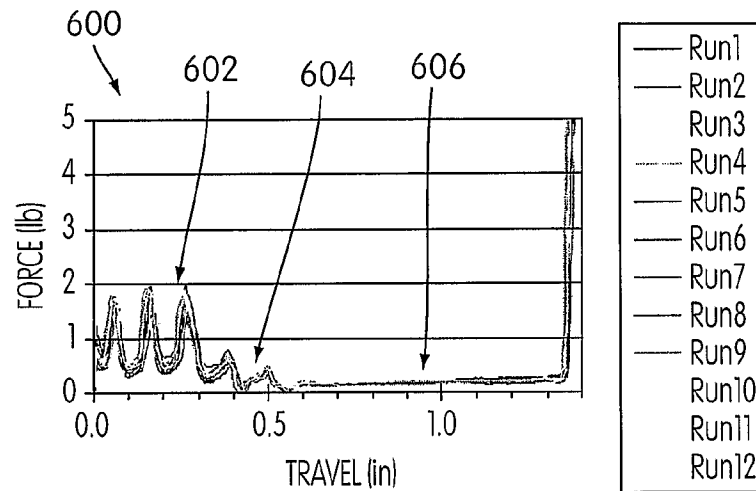


FIG. 6

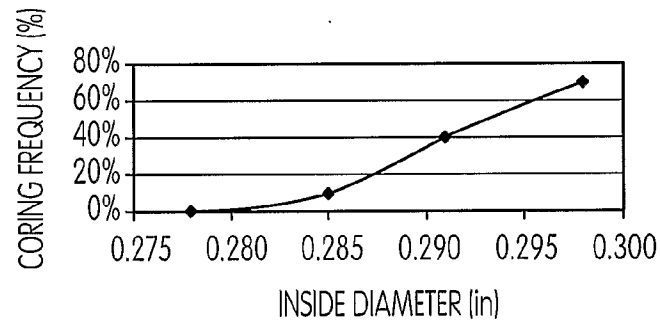


FIG. 7

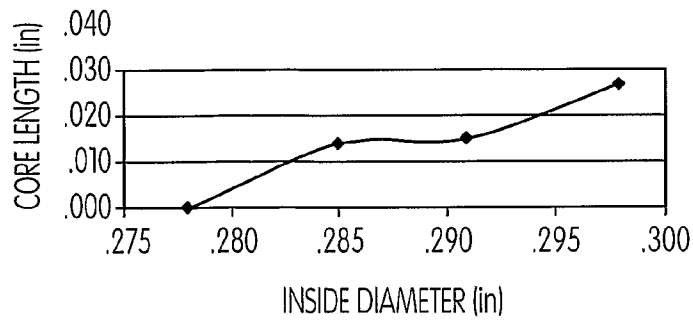


FIG. 8

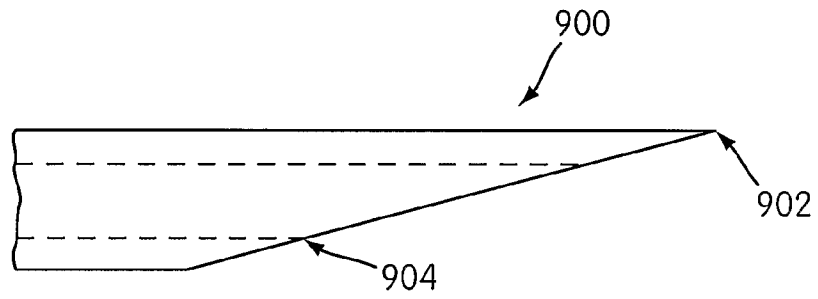


FIG. 9

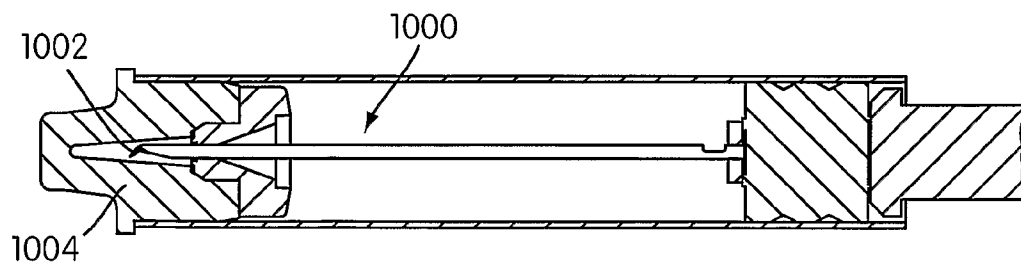


FIG. 10

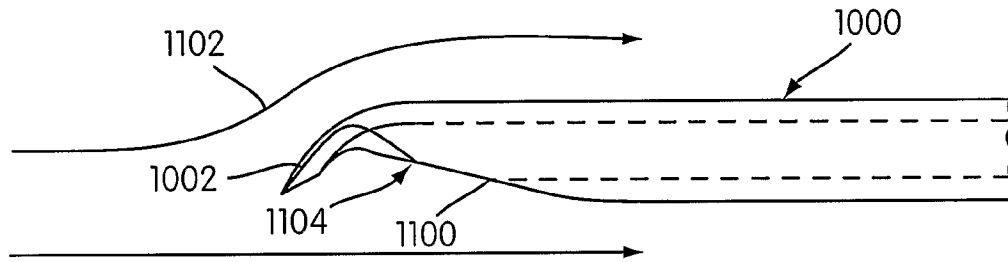


FIG. 11A

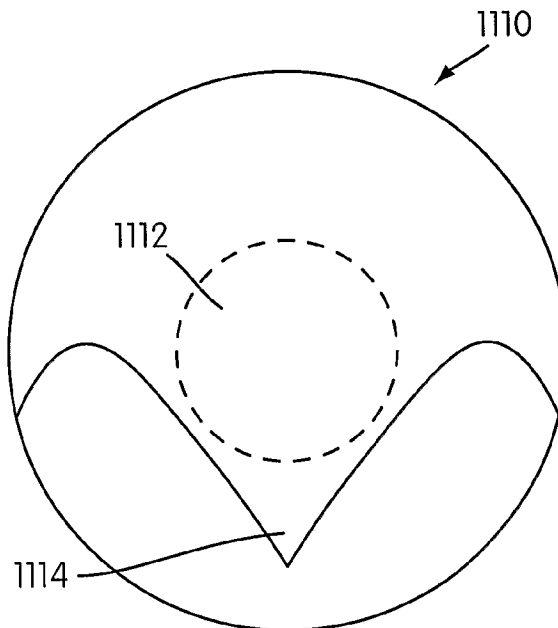


FIG. 11B

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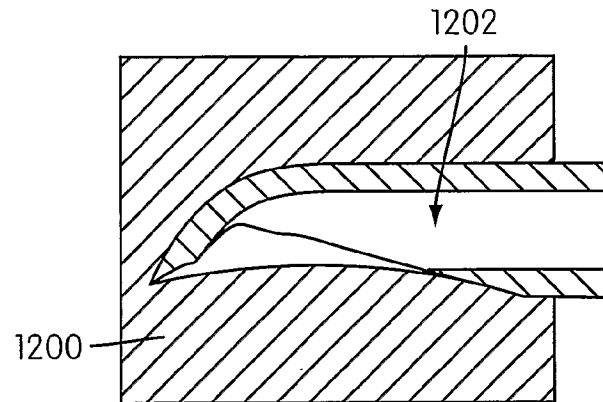


FIG. 12

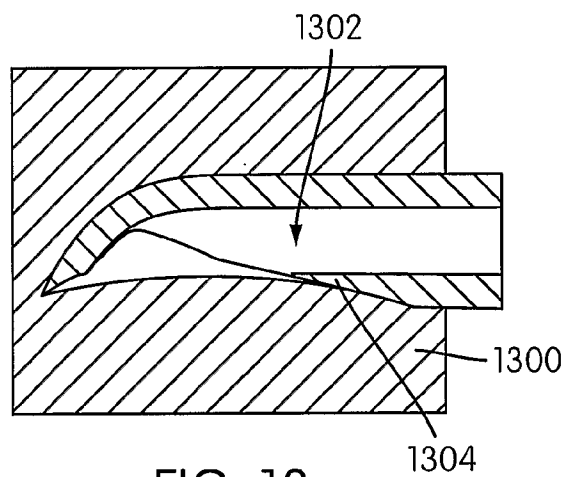


FIG. 13

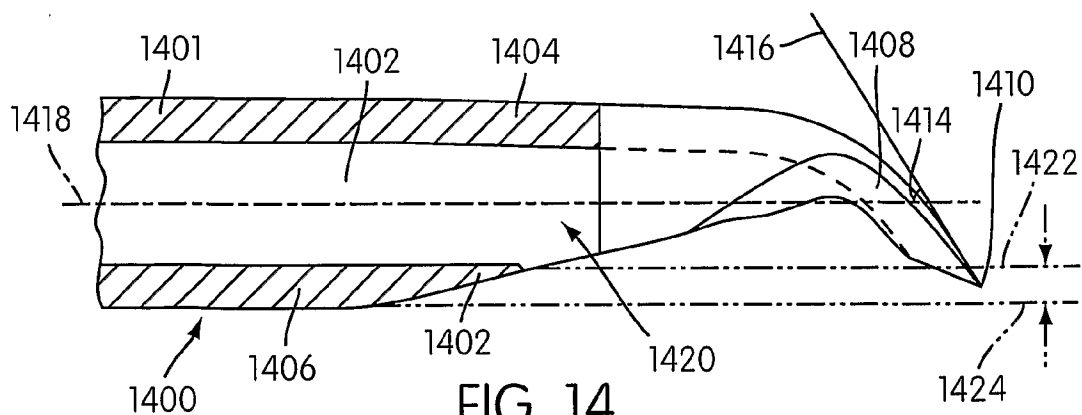


FIG. 14

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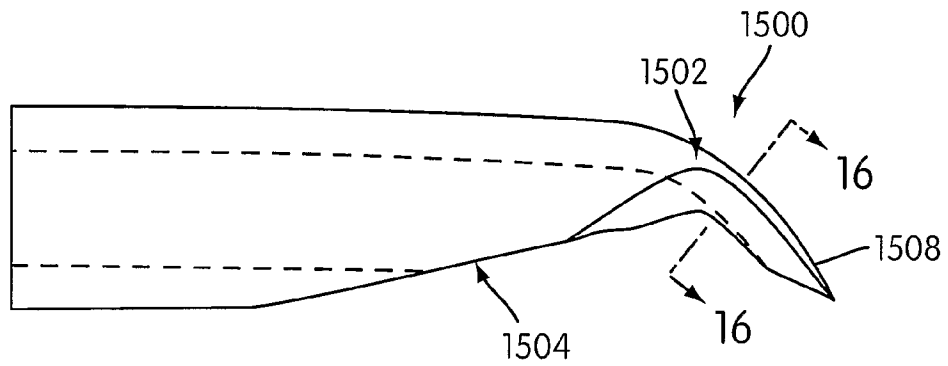


FIG. 15

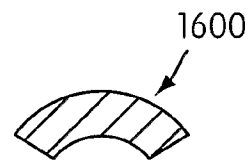


FIG. 16

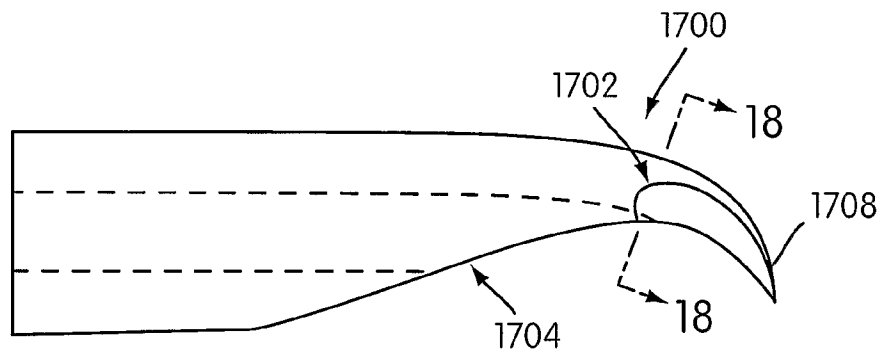


FIG. 17

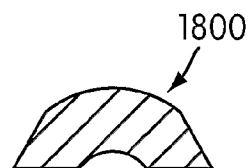


FIG. 18

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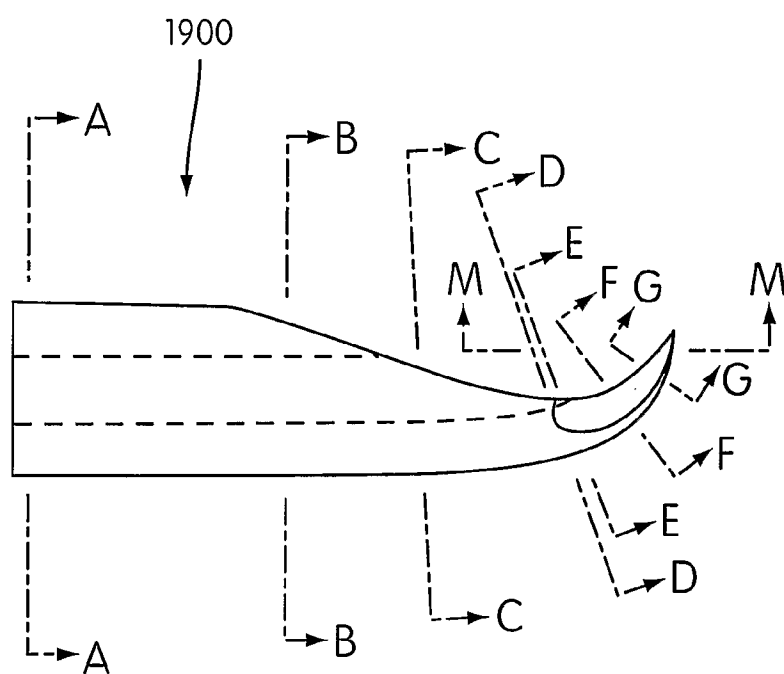


FIG. 19

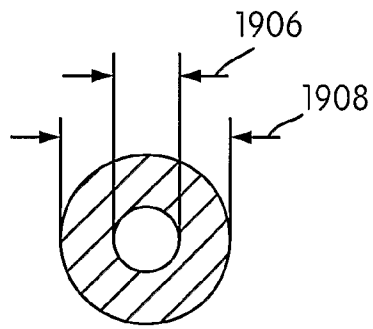


FIG. 19A

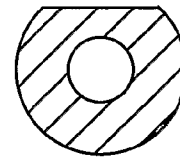


FIG. 19B

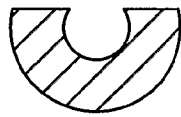


FIG. 19C

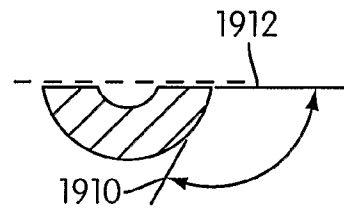


FIG. 19D



FIG. 19E



FIG. 19F



FIG. 19G



FIG. 19M

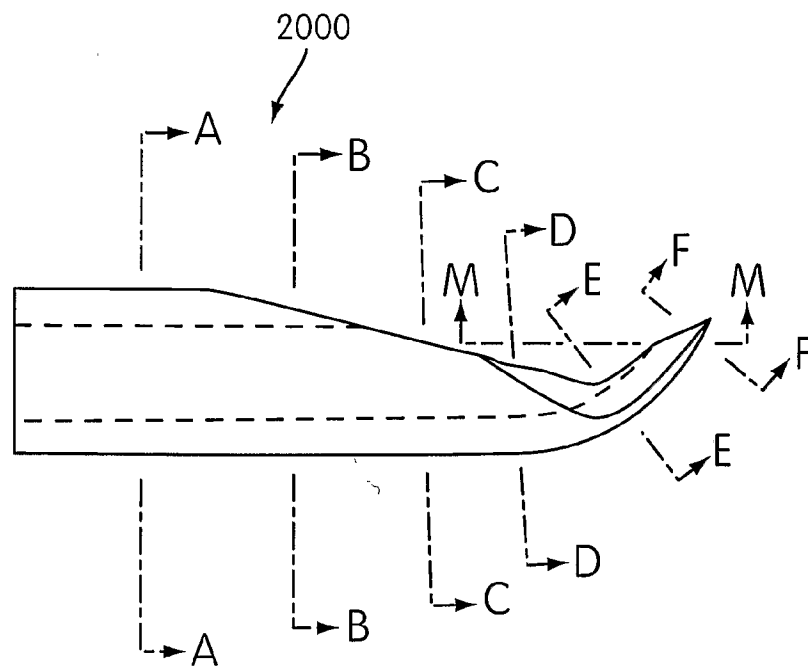


FIG. 20

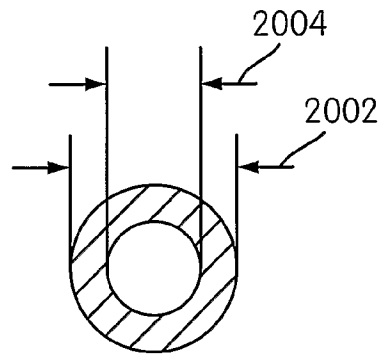


FIG. 20A

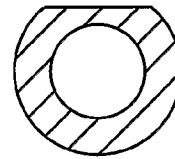


FIG. 20B

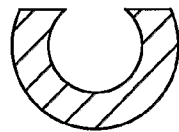


FIG. 20C

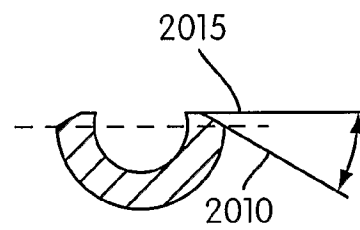


FIG. 20D



FIG. 20E



FIG. 20F



FIG. 20M

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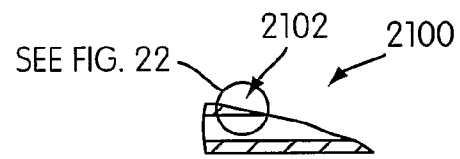


FIG. 21

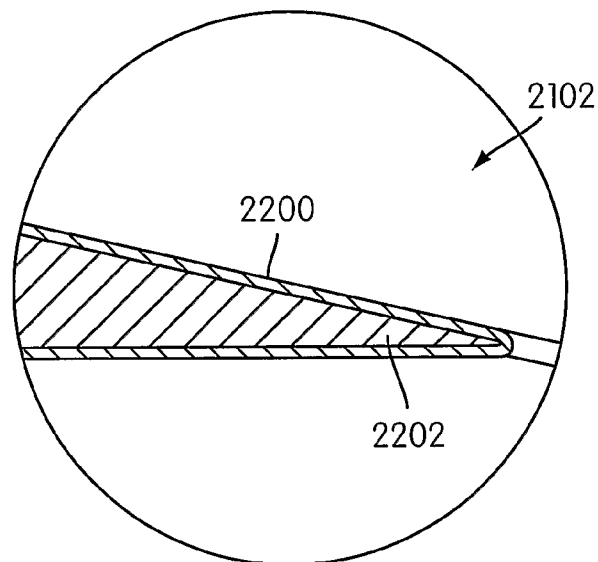


FIG. 22

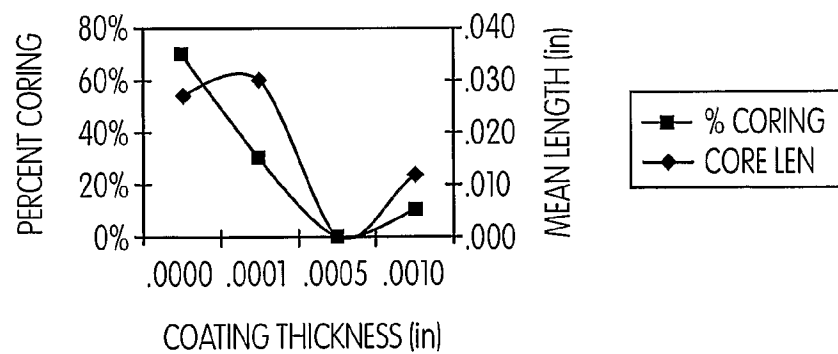


FIG. 23

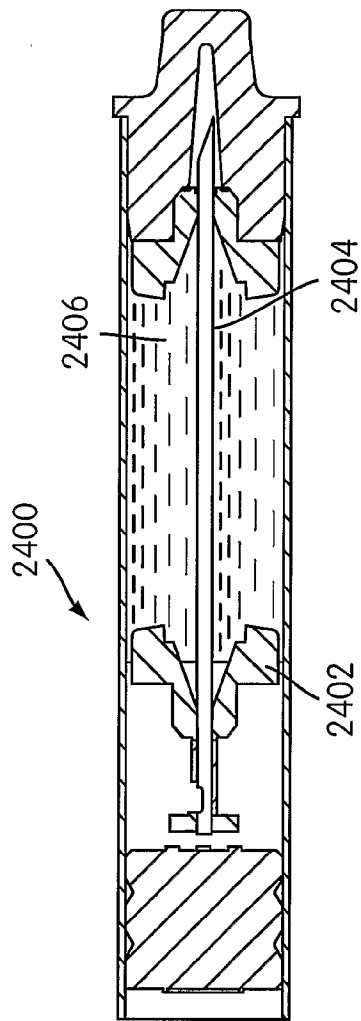


FIG. 24

(19) World Intellectual Property
Organization
International Bureau



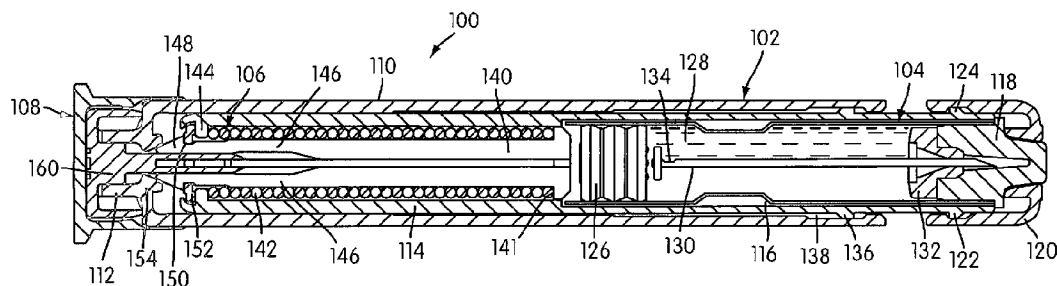
(43) International Publication Date
15 May 2003 (15.05.2003)

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(10) International Publication Number
WO 2003/039633 A3

- (51) International Patent Classification⁷: **A61M 5/20**, 5/28, 5/32 (74) Agents: **BARUFKA, Jack, S.** et al.; Pillsbury Winthrop LLP, 1600 Tysons Boulevard, McLean, VA 22102 (US).
- (21) International Application Number: PCT/US2002/035215 (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (22) International Filing Date: 4 November 2002 (04.11.2002)
- (25) Filing Language: English
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- (30) Priority Data: 09/985,466 2 November 2001 (02.11.2001) US (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant: **MERIDIAN MEDICAL TECHNOLOGIES, INC.** [US/US]; 10240 Old Columbia Road, Columbia, MD 21046 (US).
- (72) Inventors: **WILMOT, John, G.**; 7501 Mayfair Court, Mount Airy, MD 21771 (US). **WHITTIER, John**; 5410 Killingworth Way, Columbia, MD 21044 (US). **HILL, Robert, L.**; 239 Ellerslie Court, Abingdon, MD 21009 (US). **CAIN, Seth, P.**; 110 W. Fort Avenue, Baltimore, MD 21230 (US). **MESA, C., Michael**; 17505 Moore Road, Boyds, MD 20841 (US).
- Published:
— with international search report
- (88) Date of publication of the international search report: 15 January 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AUTOMATIC INJECTOR WITH ANTI-CORING NEEDLE



(57) Abstract: The automatic injector (100) comprises a cartridge (104) adapted to contain a charge of medicament, a seal structure (118) disposed toward a forward end of the cartridge, a plunger (126) normally disposed in a generally rearward end of the cartridge and movable through the cartridge toward a generally forward end thereof in response to an actuating procedure. The movable plunger rearwardly confines the medicament within the cartridge. A needle (130) normally disposed in communication with the medicament container provides a passage in which the medicament is released into an individual's flesh in response to an actuating procedure projecting the needle into the flesh of the individual. The cartridge having an increased friction region (215) so as to slow the motion of the plunger when the forward end of the needle travels through the seal in order to eliminate coring.

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INTERNATIONAL SEARCH REPORT

International Classification No
PCT/US 02/35215

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M5/20 A61M5/28 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 354 286 A (MONROE O NAPOLEON ET AL) 11 October 1994 (1994-10-11) cited in the application the whole document	1-7, 11-17, 20-23
A		18, 24, 26, 28, 30, 32 34
X	---	
Y	US 4 969 877 A (KORNBERG ELLIOT) 13 November 1990 (1990-11-13) column 5Y column 5, line 51 -column 9, line 5; figures 1-9B	1-7, 11-17

	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

16 October 2003

Date of mailing of the international search report

30. 10. 2003

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 709 668 A (WACKS JONATHAN L) 20 January 1998 (1998-01-20) column 7, line 17 -column 9, line 29; figures 1-58	1-17,24, 26,28, 30,32,34
Y	---	20
A	US 6 004 300 A (BROD SANDRA CRANE ET AL) 21 December 1999 (1999-12-21) abstract	11-14
A	US 5 290 267 A (ZIMMERMANN MICHAEL) 1 March 1994 (1994-03-01) the whole document	8-10,24, 26,28, 30,32
Y	---	20-23
A	DE 42 26 476 C (HAINDL HANS) 12 August 1993 (1993-08-12) column 2, line 48 -column 3, line 5; figures 1-4	8-10,24, 26,28, 30,32
Y	---	20
A	US 4 889 529 A (HAINDL HANS) 26 December 1989 (1989-12-26) the whole document	8-10,20, 24,26, 28,30,32
A	US 4 394 863 A (BARTNER ELLIOT) 26 July 1983 (1983-07-26) column 5, line 1-61; figures 1,2	3,12
A	WO 01 23020 A (HUGO ROBERT ;DOUGLAS JOEL S (US); RAMIREZ JOHN (US); STERLING MEDI) 5 April 2001 (2001-04-05) page 20, line 4-25	1
A	EP 1 090 651 A (CROSS SITE TECHNOLOGIES ;POUDRES & EXPLOSIFS STE NALE (FR)) 11 April 2001 (2001-04-11) column 4, line 44 -column 5, line 1 column 5, line 17-37; figures 1,2	1
X	WO 92 20388 A (MEDIMECH INT LTD) 26 November 1992 (1992-11-26) the whole document	18,19
X	US 4 968 302 A (SCHLUTER EBERHARDT ET AL) 6 November 1990 (1990-11-06) the whole document	18,19

INTERNATIONAL SEARCH REPORT

Interr application No.
PCT/US 02/35215

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 35-39
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-17, 34

Automatic injector comprising housing, seal, cartridge with medicament, plunger, needle, and releasable energy source, where the cartridge has an increased friction region, and automatic injector comprising housing, seal, cartridge with medicament, plunger, needle, and releasable energy source, where the releasable energy source is a spring.

2. Claims: 18-19

Automatic injector comprising housing, seal, cartridge with medicament, plunger, needle, and releasable energy source, where the needle has a damping structure.

3. Claims: 20-33

Automatic injector comprising housing, seal, cartridge with medicament, plunger, needle, and releasable energy source, where the needle has a bent forward tip.

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/US 02/35215

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5354286	A	11-10-1994	AU 1289495 A DE 69430210 D1 DE 69430210 T2 EP 0732950 A1 IL 111900 A WO 9515777 A1	27-06-1995 25-04-2002 10-10-2002 25-09-1996 13-07-1997 15-06-1995
US 4969877	A	13-11-1990	US 4915699 A	10-04-1990
US 5709668	A	20-01-1998	US 5360410 A US 5354287 A WO 9639213 A1 AT 173643 T AU 671322 B2 AU 5296293 A BR 9305659 A CA 2125179 A1 CN 1085107 A ,B CZ 9401620 A3 DE 69322249 D1 DE 69322249 T2 DK 616541 T3 EG 20095 A EP 0616541 A1 ES 2124325 T3 FI 942634 A HU 69509 A2 IL 107038 A JP 7501964 T LV 10204 A ,B MX 9306168 A1 NO 942020 A NZ 256977 A RO 112088 B1 RU 2127131 C1 TR 27115 A WO 9407553 A1 AU 668099 B2 AU 2476792 A CA 2114556 A1 EP 0598055 A1 JP 7501234 T KR 134789 B1 WO 9302720 A1	01-11-1994 11-10-1994 12-12-1996 15-12-1998 22-08-1996 26-04-1994 26-11-1996 14-04-1994 13-04-1994 16-11-1994 07-01-1999 22-04-1999 09-08-1999 31-07-1997 28-09-1994 01-02-1999 03-06-1994 28-09-1995 15-04-1997 02-03-1995 20-10-1994 31-01-1995 02-08-1994 27-08-1996 30-05-1997 10-03-1999 08-09-1994 14-04-1994 26-04-1996 02-03-1993 18-02-1993 25-05-1994 09-02-1995 14-04-1998 18-02-1993
US 6004300	A	21-12-1999	NONE	
US 5290267	A	01-03-1994	DE 4101231 A1 DE 59102503 D1 EP 0495214 A1 ES 2057726 T3 JP 3176413 B2 JP 4309369 A	23-07-1992 15-09-1994 22-07-1992 16-10-1994 18-06-2001 30-10-1992
DE 4226476	C	12-08-1993	DE 4226476 C1 WO 9403223 A1 EP 0655006 A1 JP 7509634 T	12-08-1993 17-02-1994 31-05-1995 26-10-1995

INTERNATIONAL SEARCH REPORT

information on patent family members

Internatic

lication No

PCT/US 02/35215

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4889529	A	26-12-1989	AT 72403 T	15-02-1992
			AT 99177 T	15-01-1994
			DE 3868298 D1	19-03-1992
			DE 3868298 T	19-03-1992
			DE 3886779 D1	10-02-1994
			EP 0301246 A1	01-02-1989
			EP 0443630 A1	28-08-1991
			ES 2028192 T3	01-07-1992
			ES 2050000 T3	01-05-1994
			JP 1027551 A	30-01-1989
			JP 1854070 C	07-07-1994
			JP 5060753 B	02-09-1993
US 4394863	A	26-07-1983	NONE	
WO 0123020	A	05-04-2001	AU 7839900 A	30-04-2001
			DE 10048220 A1	10-05-2001
			DE 20016779 U1	12-04-2001
			IE 20000785 A1	30-05-2001
			JP 2003510135 T	18-03-2003
			WO 0123020 A2	05-04-2001
			US 2002151855 A1	17-10-2002
			US 6482186 B1	19-11-2002
			AU 3285301 A	31-07-2001
			EP 1248657 A1	16-10-2002
			WO 0152925 A1	26-07-2001
EP 1090651	A	11-04-2001	FR 2799374 A1	13-04-2001
			EP 1090651 A1	11-04-2001
			US 6537245 B1	25-03-2003
WO 9220388	A	26-11-1992	AU 1926792 A	30-12-1992
			CA 2102920 A1	14-11-1992
			EP 0584207 A1	02-03-1994
			WO 9220388 A1	26-11-1992
			IE 921509 A1	18-11-1992
US 4968302	A	06-11-1990	DE 3622399 A1	04-02-1988
			AT 63697 T	15-06-1991
			AU 614264 B2	29-08-1991
			AU 7584187 A	29-01-1988
			BG 49043 A3	15-07-1991
			CA 1295902 C	18-02-1992
			CN 87105155 A , B	13-01-1988
			DE 3644984 A1	07-07-1988
			DE 3770228 D1	27-06-1991
			WO 8800066 A1	14-01-1988
			EP 0261318 A1	30-03-1988
			HU 47038 A2	30-01-1989
			JP 1500492 T	23-02-1989
			LT 2112 R3	15-07-1993
			LV 5188 A3	10-10-1993
			RO 100331 A2	18-09-1991
			SU 1716950 A3	28-02-1992
			TR 23387 A	29-12-1989
			ZA 8704715 A	07-01-1988